

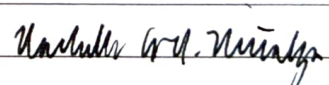

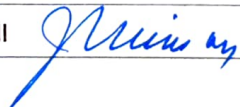


Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 27.0 Communicating IR-EC Decision  
to Principal Investigator**

Effective Date:  
**JUN 25 2021**

## PCMC IR-EC SOP 27.0: Communicating IR-EC Decision to Principal Investigator

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Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
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## **27.0 COMMUNICATING IR-EC DECISION TO PRINCIPAL INVESTIGATOR**

### **27.1 Policy Statement**

The IR-EC shall issue the decisions/actions 7 working days after the Committee meeting or an expedited review. Specific decisions/actions on protocol during a meeting shall be approved during that meeting. Recommendations shall specify actions required from the researcher.

### **27.2 Purpose of the Activity**

To provide guidance to the researcher based on the Committee decision in a timely fashion.

### **27.3 Scope**

This SOP includes the procedures for communication the IR-EC decision to the principal investigator that begins from the preparing decision letter / approval notice to the principal investigator and ends with the updating of the protocol database.

### **27.4 Process Flow/Steps for Communicating IR-EC Decision to Principal Investigator**

<b>NO.</b>	<b>ACTIVITY</b>	<b>PERSON/S RESPONSIBLE</b>
1	Preparing Decision Letter / Approval Notice to PI	IR-EC Secretariat, Chair
2	Sending Decision Letter / Approval Notice to PI	IR-EC Secretariat
3	Filing Decision Letter / Approval Notice to PI	IR-EC Secretariat
4	Updating protocol database	IR-EC Secretariat

### **27.5 Detailed Instructions**

#### **27.5.1 Preparing Decision Letter / Approval Notice to PI**

**27.5.1.1** Based on the final version of the Meeting Minutes, the IR-EC Secretariat shall prepare the IR-EC communication to the PI in duplicate copies using the standard SOP template.

**27.5.1.2** For the Decision Letter, the IR-EC Secretariat shall copy the list of recommendations from the meeting minutes to communicate them to the PI.



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- 27.5.1.3** The IR-EC Chair shall sign and date the Decision Letter / Approval Notice
- 27.5.1.4** All Decision Letters / Approval Notice shall be ready within 7 days after the meeting date for full board or 7 days after receipt of expedited review results.

**27.5.2 Sending Decision Letter / Approval Notice to PI**

- 27.5.2.1** The IR-EC Secretariat shall inform the PI/Research Assistant that the original Copy of the Decision Letter or Approval Notice is ready for pick-up.
- 27.5.2.2** The IR-EC Secretariat may email a scanned copy of the Decision Letter / Approval Letter to the PI.
- 27.5.2.3** The IR-EC Secretariat shall log the Decision Letter / Approval Notice in the Log of Outgoing Document when the original copies are released.

**27.5.3 Filing Decision Letter / Approval Notice to PI**

- 27.5.3.1** The IR-EC Secretariat shall file a duplicate copy of the Decision Letter /Approval Notice in the protocol file folder and shall update the Protocol File Index.

**27.5.4 Updating protocol database**

- 27.5.4.1** The IR-EC Secretariat shall update the protocol database.

**27.6 Forms**

Form 10.3 V.3.0 Notice of Research Protocol Approval  
Form 26.1 V.2.0 Decision Letter

**27.7 Glossary**